Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Original) A kit for determining a concentration of a vitamin D component comprising:
a releasing composition; and
a detecting composition,
the releasing composition comprises an aqueous base component and facilitates in releasing the vitamin D component from a vitamin D component binding-protein, the detecting composition facilitates in determining the concentration of the vitamin D component.

2. (Original) A kit of claim 1 being useful for determining the concentration of the vitamin D component present in a mammal fluid.

3. (Currently amended) A kit of claim ~~1~~ 2 wherein the mammal fluid is selected from the group consisting of milk, whole blood, serum, plasma and mixtures thereof.

4. (Currently amended) A kit of claim ~~1~~ 2 wherein the mammal fluid comprises a human serum.

5. (Original) A kit of claim 1 wherein the vitamin D component is selected from the group consisting of a metabolite of vitamin D2, D3, D4, D5, and D6.

6. (Original) A kit of claim 1 wherein the vitamin D component comprises a 25-OH-D.

7. (Original) A kit of claim 1 wherein the vitamin D component comprises a 1, 25-(OH)2-D.

8. (Original) A kit of claim 1 wherein the aqueous base component comprises NaOH.

9. (Original) A kit of claim 1 wherein the aqueous base component comprises KOH.

10. (Original) A kit of claim 1 wherein the releasing composition comprises about 0.1 to about 1.0 M of the aqueous base component.

11. (Original) A kit of claim 1 wherein the releasing composition comprises about 0.35 to about 0.5 M of the aqueous base component, wherein the aqueous base component is NaOH.

12. (Original) A kit of claim 1 wherein the releasing composition is substantially free of an organic solvent.

13. (Original) A kit of claim 1 wherein the releasing composition further comprises a cyclo-oligomer component.

14. (Original) A kit of claim 13 wherein the cyclo-oligomer component comprises a cyclodextrin.

15. (Original) A kit of claim 13 wherein the cyclo-oligomer component is selected from the group consisting of alpha-cyclodextrin and beta-randomly methylated cyclodextrin.

16. (Original) A kit of claim 13 wherein the releasing composition comprises about 0.01 to about 5% of the cyclo-oligomer component.

17. (Original) A kit of claim 13 wherein the releasing component comprises about 2% of the cyclo-oligomer component, wherein the cyclo-oligomer component is an alpha-cyclodextrin.

18. (Original) A kit of claim 13 wherein the releasing component comprises about 0.05% of the cyclo-oligomer component, wherein the cyclo-oligomer component is a beta-randomly methylated cyclodextrin.

19. (Original) A kit of claim 1 wherein the releasing component further comprises about 0.5 to about 5% of a metal salicylate, including sodium salicylate.

20. (Original) A kit of claim 1 wherein the releasing component further comprises about 0.01 to about 0.1% of a surfactant.

21. (Original) A kit of claim 20 wherein the surfactant is selected from the group consisting of tween-20 and triton X-100.

22. (Original) A kit of claim 1 wherein the releasing composition forms a homogeneous mixture with a mammal fluid.

23. (Original) A kit of claim 1 wherein the releasing composition comprises
about 0.1 to about 1.0 M of an aqueous base component;
about 0.01 to about 5% of a cyclo-oligomer component; and
about 0.01 to about 5% of a metal salicylate.

24. (Original) A kit of claim 23 wherein the aqueous base component is NaOH, the cyclo-oligomer component is cyclodextrin and the metal salicylate is sodium salicylate.

25. (Original) A kit of claim 1 wherein the detecting composition comprises a host component and a partner component, wherein the host component binds to the partner component to form a partner/host complex, the concentration of the complex is proportional to the concentration of the vitamin D component.

26. (Original) A kit of claim 25 wherein the host component comprises an antibody, portions thereof, or mixtures thereof.

27. (Original) A kit of claim 25 wherein the host component is labeled with a chemiluminescent label, a fluorescent label or a radio-active label.

28. (Original) A kit of claim 25 wherein the host component is an antibody labeled with acridinium.

29. (Original) A kit of claim 25 wherein the partner component comprises a vitamin D component linked to a separator component, the separator component is a solid phase or an antibody.

30. (Original) A kit of claim 29 wherein the separator component comprises a magnetic particle.

31. (Original) A kit of claim 29 wherein the partner component comprises a vitamin D component linked to a magnetic particle.

32. (Original) A kit of claim 31 wherein the partner component competes with the vitamin D component to bind to the host component.

33. (Original) A kit of claim 32 wherein the host component is an antibody labeled with acridinium.

34. (Original) A kit of claim 32 wherein the partner component binds to the host component through at least one intermediate binding component.

35. (Original) A kit of claim 34 wherein the intermediate component is labeled.

36. (Original) A kit of claim 34 wherein the intermediate component is labeled and the host component is not labeled.

37. (Currently amended) A kit of claim 34 wherein at least one intermediate binding component ~~comprise~~ comprises a vitamin D binding-protein.

38. (Original) A kit of claim 25 wherein the partner component competes with a vitamin D component to form a complex with the host component, the partner component comprises a vitamin D component linked to a magnetic particle, the partner component binds to the host component through a vitamin D binding-protein, the host component comprises an antibody labeled with acridinium.

39. (Original) A kit of claim 38 wherein the concentration of the complex is inversely proportional to the concentration of the vitamin D component.

40. (Original) A kit of claim 1 wherein the concentration of the vitamin D component is determined with a higher precision than that of an assay kit relying on an organic solvent, to release the vitamin D component from the binding-protein.

41. (Original) A kit of claim 1 wherein the releasing composition forms a homogeneous mixture with a body fluid containing the vitamin D component.

42. (Original) A kit for determining a concentration of a vitamin D component comprising:

a releasing composition comprising about 0.1 to about 1.0 M of NaOH or KOH, 0 to about 5% of a cyclodextrin, 0 to about 5% of salicylate and 0 to about 0.1% of a surfactant,

a detecting composition comprising an antibody labeled with acridinium and a partner component, wherein the partner component competes with a vitamin D component to form a complex with the antibody, the partner component comprises a vitamin D component linked to a magnetic particle, the partner component binds to the antibody through a vitamin D binding-protein.

43. (Original) A kit of claim 42 wherein the releasing composition comprises about 0.35 to about 0.5 M of NaOH, about 2% of alpha-cyclodextrin and about 2% of salicylate, the releasing composition being substantially free of an organic solvent.

44-65. Cancelled

66. (Currently amended) A method of assaying a body fluid sample ~~for the~~ to determine a concentration of a vitamin D component in the sample, the method comprising the steps of:

releasing the vitamin D component from ~~the~~ a vitamin D component binding-protein by contacting the sample with a releasing composition in a holder, the releasing composition comprising an aqueous base component, and being effective to facilitate releasing the vitamin D component from the vitamin D component binding protein; and

determining the concentration of the vitamin D component by contacting the sample with a detecting composition, the detecting composition being effective to facilitate determination of the concentration of the vitamin D component in the sample.

67. (Currently amended) A method of claim 66 wherein the vitamin D component is released into a homogeneous mixture of the body fluid sample and the releasing composition.

68. (Original) A method of claim 66 wherein the releasing composition comprises
about 0.1 to about 1.0 M of an aqueous base component;
0 to about 5% of a cyclo-oligomer component;
0 to about 5% of a metal salicylate; and
0 to about 0.1% of a surfactant.

69. (Original) A method of claim 68 wherein the aqueous base component is NaOH, the cyclo-oligomer component is cyclodextrin, the metal salicylate is sodium salicylate and the surfactant is tween-20.

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70. (Currently amended) A method of claim 66 wherein the releasing composition is substantially free of an organic solvent~~, including an organic solvent~~.

71. (Currently amended) A method of claim 67 wherein the determining step includes the steps of:

adding a detecting composition to the holder, the detecting composition comprises a host component and a partner component, the host component binds to the partner component to form a partner/host complex;

~~isolate~~ isolating the complex in the ~~tube~~ holder; and

measuring the concentration of the complex by measuring the concentration of the host component in the complex, the concentration of the complex is proportional to the concentration of the vitamin D component.

72. (Original) A method of claim 71 wherein the host component is an antibody labeled with acridinium.

73. (Original) A method of claim 72 wherein the concentration of the host is measured by detecting the emitted level of chemiluminescence.

74. (Original) A method of claim 71 wherein the partner component competes with a vitamin D component to form a complex with the host component, the partner component comprises a vitamin D component linked to a magnetic particle, the partner component binds to the host component through a vitamin D binding-protein.

75. (Currently amended) A method of claim 66 wherein the determining step includes the steps of:

adding a partner component and a vitamin D binding-protein to the tube, the partner component competes with the vitamin D component to bind to the vitamin D component binding-protein to form a partner/binding-protein complex;

~~isolate~~ isolating the partner/binding-protein complex in the holder; ~~tube; and~~

adding a host component, the host component binds to the partner/binding-protein complex to form a partner/binding-protein/host component complex; and

measuring the concentration of the partner/binding-protein/host component complex by measuring the concentration of the host component in the complex, the concentration of the complex is proportional to the concentration of the vitamin D component.

76. (Original) A method of claim 75 wherein the host component is an antibody labeled with acridinium.

77. (Currently amended) A method of claim 75 wherein the concentration of the host is measured by detecting ~~the~~ an emitted level of chemiluminescence.

78. (Original) A method of claim 75 wherein the partner component comprises a vitamin D component linked to a magnetic particle.

79. (Currently amended) A method of claim 66, wherein the method is effective to provide ~~providing~~ a more precise determination of the vitamin D component as compared to a method using a releasing composition comprising an organic solvent.

80. (Currently amended) A method of assaying a body fluid sample ~~for the~~ to determine a concentration of a 25-OH-D component in the sample, the method comprising the steps of:

releasing the 25-OH-D from the 25-OH-D binding-protein by contacting the sample with a releasing composition in a holder, including a cuvette, the releasing composition comprises about 0.1 to about 1.0 M of an aqueous base component, 0 to about 5% of a cyclo-oligomer component, 0 to about 5% of a metal salicylate, and 0 to about 0.1% of a surfactant; and

adding a detecting composition to the holder,

the detecting composition comprises an antibody labeled with acridinium, a 25-OH-D binding-protein and a partner component, the partner component comprises a 25-OH-D linked to a magnetic particle,

the partner component competes with the released 25-OH-D to bind to the 25-OH-D binding-protein to form a partner/binding-protein complex,

the antibody binds to the partner/binding-protein complex to form an antibody/binding-protein/partner component complex;

isolating the antibody/binding-protein/partner component complex in the ~~tube~~ holder; and

measuring the concentration of the antibody/binding-protein/partner component complex by measuring the concentration of the labeled antibody in the complex, the concentration of the complex is proportional to the concentration of the vitamin D component.

81. (Currently amended) A method of claim 80 wherein the concentration of the labeled antibody is measured by detecting ~~the~~ an emitted level of chemiluminescence.

82. (Original) A method of claim 80 wherein the releasing composition comprises about 0.35 to about 0.5 M of NaOH, about 2% of alpha-cyclodextrin and about 2% of salicylate.

83. (Currently amended) A method of claim 80 wherein the releasing composition is substantially free of an organic solvent~~, including an organic solvent~~.

84. (Currently amended) A method of assaying a body fluid sample ~~for the~~ to determine a concentration of a vitamin D component in the sample, the method comprising the steps of:

forming a homogeneous mixture of a body fluid sample containing the vitamin D component, and a releasing component in a holder; and

adding a detecting composition to the mixture to determine the concentration of the vitamin D component.

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